



READ CAREFULLY BEFORE USE

en PREPARATION and REPROCESSING INSTRUCTIONS according to EN ISO 17664 for users in the European Union

Scope

These instructions are designed according to EN ISO 17664 for users in the European Union and applicable to SHOFU reusable rotary dental instruments for intraoral use. All SHOFU abrasives and polishers should be cleaned and sterilized according to these instructions before first use and each subsequent reuse.

Warnings

- Chlorine disinfectant and peracetic acid must not be used to avoid corrosion of the instruments.
- Do not expose the instruments to non-approved chemical solutions (i.e., solutions not listed in these instructions).

Limitations on reprocessing

Instruments do not have an indefinite functional life. All reusable instruments are subjected to repeated stresses related to routine use, cleaning, disinfection and/or sterilization processes. The product life is determined by wear and damage caused during use. Any damaged or defective instruments must not be used (i.e., instruments with corrosion, surface flaws, deformation, dirt, exposed shank, etc.).

There is nearly no risk of cross-infection with prion diseases during normal dental treatment. However, if instruments are used for invasive treatment in patients with possible prion diseases, discard the instruments after use for incineration without reusing them.

Instructions

The reprocessing instructions described below are the procedures validated by SHOFU INC. As requirements for reprocessing procedures differ among the countries, please determine the actual procedures to be performed by giving due consideration to local regulations, with reference to the instructions below.

1. Initial treatment after use

Perform the following steps within 1 hour of the patient procedure to prevent contamination from drying on the instruments:

- Detach single-use components from the reusable components and discard the single-use components.
- Prepare an enzymatic bath using 8 mL of Advanced Sterilization Products Enzol®/Cidezyme® Enzymatic Detergent per 1 L of tap water.
- Immerse instruments for a minimum of 3 minutes.

2. Mechanical cleaning and disinfection

2-1. Preparation

The following will be required for cleaning and disinfection of the instruments:

- Soft-bristled toothbrush
- Critical water (water that is extensively treated, usually by a multistep treatment process that could include a carbon bed, softening, DI and RO or distillation)
- Non-linting wipes or cloths for drying
- neodisher® MediClean forte
- Suitable bur block
- ISO 15883 compliant washer disinfectant

2-2. Manual pre-cleaning

- Using a soft-bristled toothbrush, brush the instruments in enzymatic bath for a minimum of 30 seconds and until no visible contamination is present.
- Remove the instruments from enzymatic bath.

- Rinse the instruments under running tap water, for a minimum of 10 seconds.

2-3. Mechanical cleaning and disinfection

- Place the instruments into a bur block. Leave the block lid open and place the block on the shelf of an ISO 15883 compliant washer disinfectant.
- Perform automated cleaning and disinfection.

Validated conditions

Phase	Minimum time	Temperature	Type of detergent/water
Pre-Wash	2 minutes	Cold	Tap water
Draining			
Wash	5 minutes	Heated (55 °C)	Tap water and 0.5% (5 mL/L) neodisher® MediClean forte
Draining			
Rinse 1	3 minutes	Cold	Critical water
Draining			
Rinse 2	2 minutes	Cold	Critical water
Draining			
Thermal Disinfection	5 minutes	Heated (≥ 90 °C)	Critical water
Dry	15 minutes	Heated	

Notes:

- Cleaning and disinfection validation has been performed using Miele Professional G7836 CD washer disinfectant with vario-TD program with the parameters shown in the table above. Parameters may vary depending on the washer disinfectants.
- Thermal disinfection should be performed in accordance with ISO 15883-1. Please observe local regulations that may require a higher level of thermal disinfection.
- If needed, thoroughly dry all surfaces of the instruments using non-linting wipes or cloths, changing wipes/cloths when necessary to ensure that the instruments are completely dry.

2-4. Inspection

Visually inspect each instrument for the absence or presence of remaining contamination in a well-lit area. If contamination is present, repeat the mechanical cleaning and disinfection until all visible contamination is removed.

Note: Discard the instruments if any damage or defects (e.g., corrosion, surface flaws and/or deformations), which would prevent proper operation, are found.

3. Storage after disinfection

Instruments should be protected from contamination until sterilization. Disinfected and dried instruments should be handled and stored in a manner that protects them from recontamination.

4. Sterilization

4-1. Preparation

The following will be required for sterilization:

- EN 13060 compliant autoclave
- Suitable bur block
- ISO 11607-1 compliant pouches for steam sterilization, as applicable

4-2. Packaging

Handle instrument(s) as follows:

- Place a single instrument in a sterilization pouch in accordance with local procedures (e.g., AAMI ST79).
- Place multiple instruments in a bur block and then place the block in a sterilization pouch in accordance with local procedures (e.g., AAMI ST79).

4-3. Sterilization

Sterilize the instruments using the appropriate parameters listed below:

Procedure	Dynamic-air-removal Steam Sterilization Cycle
Holding time	≥ 3 minutes
Sterilization temperature	≥ 132 °C
Minimum drying time	20 minutes

Notes:

- As requirements for sterilization conditions (i.e., temperature and time) differ among the countries, requirements of local regulations must be observed.
- The sterilization parameters validated by SHOFU INC. in accordance with ISO 17665 series to achieve the sterility assurance level (SAL) of 10^{-6} are shown in the table below:

Validated conditions

Autoclave: Getinge K7+ Small Sterilizer
Sterilization pouch: STERIKING®
Pre-vacuum: 4 times
Holding time: 3 min
Sterilization temperature: 132 °C

5. Storage after sterilization

- Keep instruments in sterilization packaging in a dry and clean environment.
- Sterility cannot be guaranteed if packaging becomes open, damaged, or wet.
- Check the packaging and the instruments before use (packaging integrity, no excessive humidity and validity period).

Customer service

The cleaning, disinfection and sterilization information is provided in accordance with EN ISO 17664, AAMI TIR12, and AAMI TIR30.

These instructions have been validated by SHOFU INC. as being capable of preparing the rotary dental instruments for reuse. It remains the responsibility of the processor to ensure that the processing is actually performed using equipment, materials and personnel in the reprocessing facility to achieve the desired result. This requires validation and routine monitoring of the process. Likewise, any deviation by the processor from the recommended process in these instructions should be properly evaluated for effectiveness with potential adverse consequences.

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